

REMARKS

Support for the Amendments

The amendment to claim 1 is supported by claim 11. The amendment to claim 23 is supported by claims 1 and 24. The amendment to claims 42 and 44 is supported, for example, on page 111, lines 17-21 (M.P.E.P. § 2173.05(i)).

The Office Action

Claims 1-30 and 39-44 are pending. Claims 1-10, 19, 20, 22, 27, and 30 stand rejected for anticipation by Becerra et al. (Magn Reson Med 1999 41:1044; hereafter “Becerra”). Claims 1-10, 22, 28, 29, and 39-44 stand rejected for anticipation by Wu et al. (Neuroradiology 1999 212:133; hereafter “Wu”). Claims 1-10, 22, 27, 39, and 40 stand rejected for anticipation by Tolle et al. (Annals of Neurology 1999 45:40; hereafter “Tolle”). Claims 1-10, 19, 20, 22, 23, 30, 39, and 40 stand rejected for anticipation by Iadorola et al. (Brain 1998 121:931; hereafter “Iadorola”). Claim 21 stands rejected for obviousness over Becerra, Wu, Tolle, or Iadorola in view of Sodickson (U.S. Patent No. 5,910,728). Claims 1, 39, 41, 42, and 44 stand rejected for lack of enablement and are also objected to for informalities. Claims 11-18 and 24-26 would be allowable if written in independent form. The drawings are objected to for failing to show elements 100 and 118.

The Drawings

Applicants enclose herewith proposed corrections to Figure 3 that show elements 100 and 118 as requested by the Office. If these amendments are acceptable, Applicants will provide corrected drawings in reply to the next action.

Claim Objections

Claims 1, 39, 41, 42, and 44 are objected to for informalities. Claim 1 has been amended to contain the limitations of claim 22, as suggested by the Examiner, and the objection may be withdrawn. Claims 39 and 41 are cancelled. Claims 42 and 44 are objected to for lacking a step corresponding to evaluating the efficacy of a treatment for pain. These claims have now been amended to recite “thereby evaluating the efficacy of the treatment for pain,” and the objection may be withdrawn. In addition, claims 42 and 44 are objected to for lacking a step that requires “correlation with physiological and psychological data.” Claims 42 and 44 have now been amended to include such a step, and the objection may be withdrawn. Finally, the phrase “from the same at least two different” in claim 42 that is objected to by the Office has been amended to recite “from the at least two different,” and this objection may also be withdrawn.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 1, 39, 41, 42, and 44 stand rejected for lack of enablement. Regarding claim 1, the Office states that “[t]he specification does not teach how to correlate signals

in a reward/aversion region to a type of pain absent an applied stimulus.” Claim 1 has now been amended to recite the step of “applying a reward/aversion stimulus to the subject to elicit the response,” and the rejection may be withdrawn. As stated above, claims 39 and 41 are cancelled. Regarding claims 42 and 44, the Office states that “[t]he specification does not teach how to correlate the effect of a drug to a reward/aversion region of the brain absent physiological and psychophysical data...” Also as stated above, claims 42 and 44 have been amended to recite such a step, and this rejection may be withdrawn.

Rejections under 35 U.S.C. § 102

Claims 1-10, 19, 20, 22, 27, and 30 stand rejected for anticipation by Becerra. Claims 1-10, 22, 28, 29, and 39-44 stand rejected for anticipation by Wu. Claims 1-10, 22, 27, 39, and 40 stand rejected for anticipation by Tolle. And claims 1-10, 19, 20, 22, 23, 30, 39, and 40 stand rejected for anticipation by Iadorola. Claims 22 and 39-41 have been cancelled. Applicants reserve the right to pursue the cancelled matter in later filings. Applicants traverse the rejections as applied to the remaining amended claims.

Applicants have amended claim 1, from which claims 2-10, 19, 20, and 27-30 depend, to include the limitations of claim 11. As the Office has indicated that claim 11 is allowable over the cited art, the rejection of claims 1-10, 19, 20, and 27-30 is now moot.

The Office rejected claim 23 over Iadarola without making any specific arguments regarding the limitations of this claim. Anticipation requires a reference that teaches every element of a claim (M.P.E.P. § 2131). Amended claim 23 is directed to a method of determining the effect of a compound on pain in a subject and recites the step of “administering to a subject at least one of: a drug, a gene product, a biopharmaceutical, a virus, a gene, one or more receptors, and a neurochemical.” Iadarola does not administer one of a drug, a gene product, a biopharmaceutical, a virus, a gene, one or more receptors, and a neurochemical to determine its effect on pain in a subject. Iadarola only administers capsaicin to induce pain in a subject, not to determine its effect. Thus Iadarola does not teach every element of claim 23, and the rejection for anticipation should be withdrawn.

The remaining independent claims, 42 (from which claim 43 depends) and 44 stand rejected for anticipation by Wu, with the Office stating “Wu et al. teaches a method for correlating and mapping signals in a reward/aversion brain region, such as the NAc, to a ‘type’ of pain … in conjunction with treatment such as acupuncture.” As stated above, anticipation requires a reference that teaches every element of a claim. Wu does not meet this standard with respect to amended claims 42 and 44, which are directed to methods for evaluating the efficacy of a treatment for pain, excluding acupuncture. The only potential treatment disclosed by Wu is acupuncture. As acupuncture is now specifically excluded from evaluation in the instant claims, Wu cannot teach all of the limitations of claims 42 and 44, and the rejection of these claims for anticipation should be withdrawn.

Rejections under 35 U.S.C. § 103

Claim 21 stands rejected for obviousness over Becerra, Wu, Tolle, or Iadorola in view of Sodickson. Claims 21 depends from amended claim 1, which includes the limitations of now cancelled claim 11. As the invention of claim 11 has been determined to be unobvious over the cited art, the rejection of claim 21 may also be withdrawn.

Information Disclosure Statement

In response to the Examiner's inquiry, Becerra et al. "Early Activation of Reward/Aversive Circuitry Following Noxious Thermal Stimuli..." was published in December 2001, Breiter et al. "Morphine Activates Reward Circuitry in the Human Brain" has not been published, Carelli et al. J. Neurosci. 20:4255-4266 was published in June 2000, Gur et al, Psychiatry Research 42:241-251 was published in 1992, and Yoshida et al. Neuroscience Letters 139:73-76 was published in 1992. A copy of the PTO Form-1449 submitted on September 17, 2001, with dates added as appropriate, has been provided. Applicants request that it be initialed and returned with the next Office action.

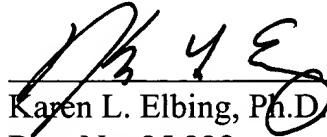
CONCLUSION

Applicants submit that the claims are in condition for allowance and such action is respectfully requested. Enclosed is a petition to extend the period for reply for three

months, to and including July 29, 2004. If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: 29 July 2004



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PATENT & TRADEMARK OFFICE

Title: METHOD AND APPARATUS FOR OBJECTIVELY
MEASURING PAIN, PAIN TREATMENT AND OTHER RELATED
TECHNIQUES

Applicant: Bacerra et al.
Filing Date: July 29, 2004
Page 1 of 1

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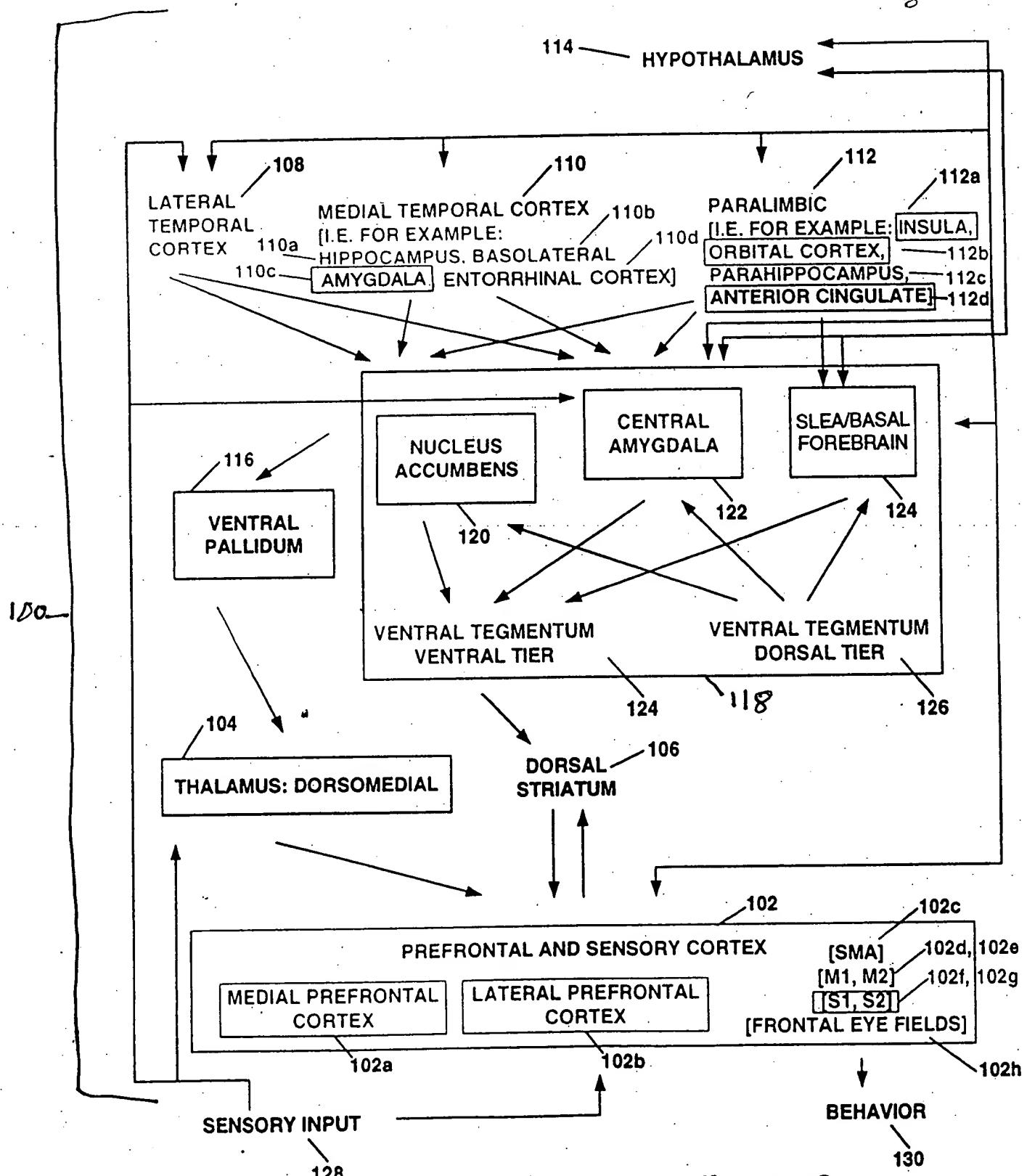


Figure 3